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|--|-------------|----------------------|---------------------|------------------|
| 10/804,096   | 03/19/2004  | Pierre Marraccini    | 112701-535          | 7981             |
| 29157  | 7590        | 07/13/2005           | EXAMINER            |                  |
| BELL, BOYD & LLOYD LLC<br>P. O. BOX 1135<br>CHICAGO, IL 60690-1135 |             |                      | KOROMA, BARBA M     |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1638                |                  |
| DATE MAILED: 07/13/2005  |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/804,096

Applicant(s)

MARRACCINI ET AL.

Examiner

Barba M. Koroma

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 12-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. The text of those sections of Title 35, US Code not included in this action can be found in a prior action.
2. Applicant's response filed 5/2/05 in reply to Office Action mailed 1/28/05 has been entered. Claims 8 and 9-11 have been withdrawn. Claim 7 is amended. Claims 1-7, and 12-14 are under consideration in the action.
3. Withdrawn claims must be cancelled by Applicant in response to this Office Action.
4. This Office action contains NEW GROUNDS OF REJECTIONS not necessitated by Applicant's amendments. Therefore, this action is non-final. The delay in applying these grounds of rejection is regretted.
5. Rejections in the previous Office directed to withdrawn claims are hereby withdrawn.
6. Examiner hereby acknowledges submission of International Search Report: PCT/EP02/09148, entered on 3/19/04. Objection relating to the submission of this document is hereby withdrawn.

**Claim Rejection 35 USC 102b**

7. In view of the amendment of claim 7, the rejection is hereby withdrawn.

**Objections to Specification**

8. Objections to the specification have been withdrawn in light of Applicant's amendments of the specification.

**Claim Rejections 35 USC 112 Second paragraph**

9. In light of explanation (Applicant response, page 5, 3<sup>rd</sup> paragraph), and amendment to claim 7 of pending claims, rejections based on 35 USC 112 second paragraph have been withdrawn.

**Claim Rejections - 35 USC 112. *First Paragraph - Enablement***

10. Claims 1-7, and 12-14, are rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected, to make and use the invention. The specification fails to teach a transformed plant with reduced galactosidase activity, increased galactose branching, and increased solubility of coffee. The rejection is maintained for the reasons of record as set forth in the Office Action of 1/28/05. Applicant's arguments filed on 5/2/05 have been considered but not found persuasive.

Applicant argues that one having ordinary skill in the art would be able to make and use the present invention based on Applicant's specification, that the specification provides adequate guidance to one of ordinary skill in the art on how to make and use the present claims for a transformed plant with reduced endogenous  $\alpha$ -D-galactose activity and increased galactose

branching resulting in increased solubility of coffee (response, page 5, 4 and 5<sup>th</sup> paragraphs, page 6, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs).

Examiner maintains that the specification as filed is not enabling and that the arguments as presented are not tenable because claim 1, drawn to modification of a galacto-mannans - producing coffee plant by any means, to reduce endogenous levels of  $\alpha$ -D-galactosidase activity in order to increase galactose branching of the galacto-mannans, does not limit the modification process to any specified methods. This invites trial and error experimentation involving highly unpredictable methods, none of which is guaranteed to produce the desired outcome. This is compounded by the fact that the specification itself fails to teach a plant that has been modified to produce the claimed phenotype.

Applicant also argues that the use of an antisense construct “should” (emphasis added) reduce the level of expression of the corresponding gene, and acknowledges the earlier grounds for rejection by stating that “As patent office recites, this may not always be the case, and the level of repression may be variable and unpredictable”, that “there is evidence that the construct works at some levels” (response, page 6, 2<sup>nd</sup> paragraph).

Claim 2 recites “containing a nucleic acid that is transcribed to a ribonucleic acid which is antisense to mRNA, or part thereof, derived from the  $\alpha$ -D-galactosidase gene of the cell”. As indicated in the previous office action, the antisense inhibition of endogenous gene expression is not foolproof. In other words, it can be highly unpredictable. The phrase “antisense to mRNA or **part thereof**” (emphasis added) in claim 2 was not described and not enabled. Absent this teaching, the specification remains non-enabled. Thus, one of ordinary skill in the art will not

Art Unit: 1638

know how to make and use the invention as claimed. In the last line of page 12 of the specification, it is indicated that an amplification product was detected in a coffee plantlet, confirming  $\alpha$ -D-galactosidase antisense RNA. However, there is no correlation between the occurrence of antisense PCR product in a coffee plant cell, and inhibition of  $\alpha$ -D-galactosidase. Thus, not only is Applicant's assertion that "there is evidence that the construct works at some levels" (response, page 6, line 6) not fully supported by the original specification, it is a prediction that is not supported based what is known of antisense technology. Applicant is reminded that post-filing data would be considered inadmissible New Matter.

Applicants argue further that, according to MPEP, an example may be working or prophetic, that an applicant need not have actually reduced the invention to practice prior to filing, that the specification need not contain examples if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without undue amount of experimentation (response, page 6, 3<sup>rd</sup> paragraph).

In the instant case, failure of the specification to teach a plant that shows reduced endogenous levels of  $\alpha$ -D galactosidase activity in coffee plants modified by said RNA and parts thereof, failure to teach the structure part of the RNA to be targeted by the anti-sense construct, constitute an invitation to undue trial and error experimentation that promises no coffee plants with reduced endogenous  $\alpha$ -D-galactosidase activity.

Applicant's assertion that the reduction of  $\alpha$ -D galactosidase may be achieved by conventional methods of mutation and selection using the techniques available in the art

(response, last paragraph, page 6), is speculative and outside the scope of the claimed invention. Further, there is no guidance in support of such procedures in the original specification.

On page 7 (3<sup>rd</sup> paragraph), Applicant argues that “if” (emphasis added) the endogenous levels of  $\alpha$ -D-galactosidase activity was reduced, it is possible that the level of galactose units on the mannan chain would be increased and this could increase solubility and extractability, that even a small relatively effective anti-sense nucleic acid could be sufficient to give commercially relevant result in accordance with the present claims.

Applicant is reminded that a 35 USC 112 first paragraph enablement rejection is based on lack of guidance on how to make and use, and speculation does not substitute for teaching or providing guidance on how to make and use.

In summary, Applicants arguments against the 35 USC 112, First paragraph enablement, filed on 5/2/05, have been considered but not found persuasive, and the rejection is repeated for the reasons of record as set forth in the Office Action of 1/28/05.

The rejected claims would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1<sup>st</sup> paragraph, set forth in this Office action.

### **New Claim Rejections**

#### **35 USC 101**

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7, and 12-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claimed coffee plant cell, coffee plant, and coffee beans, are indistinguishable from naturally-occurring wild-type plants of the same species. Also, naturally-occurring anti-sense RNA in wild-type plants can form dimers with endogenous sequences, thereby reduce endogenous levels of galactosidase gene expression. Accordingly, the claims are drawn to a product of nature, which is non-statutory subject matter.

See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo Inoculant Co.*, 233 U.S. 127 (1948), and *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931).

#### **35 USC 112 – *Written description***

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.



Claims 1-7 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is lack of written description by the specification regarding the coffee plant cell, the coffee plant, and the coffee beans; as well as the structure of the nucleic acid (mRNA) or parts thereof, derived from the  $\alpha$ -D-galactosidase gene of the cell, contained in the coffee plant cell, coffee plant and coffee beans.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

See also MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that:

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a

functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

The claims are broadly drawn to a naturally-occurring coffee plant that contains any and all ribonucleic acids, and produces galacto-mannans.

The specification indicates that a PCR product representing  $\alpha$ -D-galactosidase was cloned into a vector (page 9, lines 12-15), which was used to transform a coffee plant (section VII, pages 10-11).

However, the specification does not describe any and all nucleic acids used to transform a coffee plant, nor does it describe any coffee plant with reduced endogenous levels of  $\alpha$ -D-galactosidase levels and increased galactose branching.

The specification fails to provide an adequate written description of the genus of nucleic acids as broadly claimed. Given the lack of written description of the claimed genus of nucleic acids and the claimed transformation methods and transgenic plants are likewise not described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing.


Art Unit: 1638

*Contact Information*

13. Any inquiry concerning this or earlier communications from the Examiner should be directed to Barba M. Koroma, whose telephone number is 571-272-0899. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571 273 8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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